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EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	PAPER NUMBER
1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,483	GIBSON ET AL.	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☒ Claim(s) *5 and 15-21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/06,4/07,5/08,2/09,4/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed October 6, 2005, has been received and entered.

Claims 1-21 are pending.

Deposit of Microorganism

It is noted that claims 5 and 15 recite a specific organism, a strain deposited under accession number NCIM 41171. While this raises an issue with respect to enablement under 35 U.S.C. 112, first paragraph, it appears that the organism is publicly available without restriction. The organism is therefore considered to be publicly available, unless applicant indicates otherwise. Should applicant become aware of any information to the contrary during the prosecution of this case, applicant must disclose such information to the office.

Claim Objections

Claims 5 and 15-21 are objected to because of the following informalities: The recitation "A" at the beginning of claim 5 should be replaced with "The." In claims 5 and 15, the recitation "31 March 2003" should be replaced with "March 31, 2003." In claim 16, in the second line, "are" should be replaced with "is." In claim 18, in the last line, "a" should be replaced with "the." In claim 19, at line 1, the recitation "lactose containing" should be replaced with "lactose-containing." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the strain deposited under accession number NCIMB 41171 and its use, does not reasonably provide enablement for any other strain of *B. bifidum* that produces the galactooligosaccharide mixtures recited in claims 3, 4, and 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Regarding undue experimentation, *In re Wands*, 8 USPQ2d 1400, at 1404 (Fed. Cir. 1988) states:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (Citations omitted).

A large quantity of experimentation would be required to determine which of the numerous known strains of *B. bifidum* convert lactose to the specific galactooligosaccharide mixtures recited in claims 3, 4, and 8. A great amount of analysis would be required to separate and analyze the galactooligosaccharides produced for lactose-containing material treated with each *B. bifidum* strain. Moreover, the specification as filed solely teaches of one working example, the strain deposited under accession number NCIMB 41171, which produces the galactooligosaccharide mixtures of claims 3, 4, and 8. Given the quantity of experimentation necessary and the presence of solely one working example, undue experimentation would be required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 7-13, 15-17, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4, 7, and 9 are indefinite because it is unclear which of the "at least one" disaccharide, trisaccharide, tetrasaccharide, and pentasaccharide recited in parent claims 1 and 6 are "the" disaccharide, trisaccharide, tetrasaccharide, and pentasaccharide recited in each of claims 2, 4, 7, and 9. Thus, claims 2-4 and 7-9 are rejected under 35 U.S.C. 112, second paragraph.

Claims 5 and 15 are rendered indefinite by the recitation "biologically functional equivalent." It is unclear from the recitation what are the metes and bounds of the claim. It is unclear what strains could be considered biologically functional equivalents of the strain deposited under accession no. NCIMB 41171.

Claims 7-13 are indefinite since it is unclear whether "the composition" is the "galactooligosaccharide composition" of parent claim 6. Thus, claims 7-13 and 15 are rejected under 35 U.S.C. 112, second paragraph. It is suggested that "the composition" be replaced with "the galactooligosaccharide composition."

Claim 16 is indefinite since it claims "Use according to Claim 14" but claim 14 refers to a strain rather than a use. Thus, claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph.

Claim 21 is indefinite since it indicates that there is a step of removal of *Bifodobacterium bifidum* cells. However, parent claim 18 does not expressly disclose that there is such a step. Therefore, it is unclear the sequence of steps of claim 21.

Claims 12, 13, and 15-17 provide for the use of the composition of claim 6 or the use of a strain of *Bifodobacterium bifidum*, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12, 13, and 15-17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-7, 10, 11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumortier et al. (Carbohydrate Research. 1990. 201: 115-123. listed on 4/4/07 IDS).

Dumortier et al. discloses a lactose solution incubated with a cell suspension of *Bifidobacterium bifidum* DSM 20456 comprising β-D-galactosidase (page 116, last paragraph) resulting in the formation of 10 galactooligosaccharides (page 117, first-third paragraphs). Various fractions from the incubation mixture were obtained, where fractions 1 and 2 comprise three different disaccharides (page 117, last paragraph and page 118, first full paragraph), fractions 3 and 4 comprise multiple trisaccharides (page 118, last paragraph and page 119), fraction 5 comprises a tetrasaccharide (page 120, second full paragraph), and fraction 6 comprises a pentasaccharide (page 120, third full paragraph). Thus, instant claim 1 is anticipated by the reference. Though Dumortier et al. does not teach a strain deposited under accession number NCIMB 41171, the strain DSM 20456 is a "biologically functional equivalent" of that strain as it can produce the oligosaccharide mixture required by claim 1. Thus, claim 5 is also anticipated.

Furthermore, instant claim 2 is anticipated given the structures on page 121 of Dumortier et al. (see the structures 3, 4, 5, and 8).

Although the reference does not specifically teach that the composition is effective for promoting specific growth of bifidobacteria, that the composition is for improving gut health, or that the composition is for use in a method of treatment of a human or animal by therapy, the compositions are the same, thus the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. As pointed out in MPEP §2112, "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable". Thus, instant claims 6, 7, 10, 11 (incubating the strain with lactose solution results in a composition comprising the strain and the galaoctooligosaccharides), and 14 are also anticipated.

A holding of anticipation is clearly required.

Claims 6 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Gibson et al. (US 2004/0131659).

The applied reference has a common assignee and a common inventor (Glenn Gibson) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Gibson et al. discloses a galacto-oligosaccharide mixture (GOS) that may comprise di, tri, tetra, and pentasaccharides. The GOS preferably comprises 33% disaccharides, 39% trisaccharides, 18% tetrasaccharides, and 0 to about 30% pentasaccharides. See page 2, paragraph [0027]. GOS along with FOS promote the growth of bifidobacteria (page 1, paragraph [0012]).

Thus, a holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5-7, 10-14, and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumortier et al. in view of Jorgensen et al. (US 2002/0086358), Ziggers (Feed Mix. 2001. 9(6): 7-9. listed on 2/25/09 IDS), and De Jong et al. (WO 00/33854).

As discussed above, Dumortier et al. anticipates claims 1, 2, 5-7, 10, 11, and 14. However, Dumortier et al. does not expressly disclose that the resulting galactooligosaccharide mixture is used for improving gut health. The reference does not teach that the galactooligosaccharide mixture is used in the preparation of a medicament for preventing adhesion of pathogens or toxins produced by pathogens to the gut wall. Moreover, it also does not teach that the galactooligosaccharide mixture is used in the preparation of a medicament for re-establishing a normal gut flora following antibiotic treatment or surgery.

Jorgensen et al. teaches that Bifidobacteria can outcompete potential harmful intestinal microorganisms (page 1, paragraph [0002]). Further still, galacto-oligosaccharides are known to enhance the growth of Bifidobacterium. See page 1, paragraph [0002]. The galacto-oligosaccharides may be used in a product selected from yogurt, cheese, fermented milk products, dietary supplements, and probiotic comestible products (page 3, paragraph [0022]).

Ziggers teaches that transgalacto-oligosaccharides (TOS) stimulate the growth of Bifidobacteria while restricting the growth and survival of many pathogenic bacteria when ingested (page 7, first paragraph).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used the Dumortier galactooligosaccharide mixture in a medicament for preventing adhesion of pathogens or toxins produced by pathogens to the gut wall. One of ordinary skill in the art would have been motivated to do this since transgalacto-oligosaccharides

(such as those present in the Dumortier galactooligosaccharide mixture) are known to restrict growth/survival of pathogenic bacteria in the gut. Moreover, as the Dumortier galactooligosaccharide mixture would have stimulated the growth of Bifidobacteria, more Bifidobacteria is present in the gut which can outcompete with potential harmful intestinal microorganisms, thus preventing their adhesion to the gut wall. Thus, claim 12 is rendered obvious.

It would have also been obvious to have used the Dumortier galactooligosaccharide mixture in a medicament for re-establishing a normal gut flora following antibiotic treatment or surgery since Bifidobaceria growth in the gut would have been stimulated by TOS such as those present in the Dumortier galactooligosaccharide mixture. Bifidobacteria is part of the normal gut flora as Jorgensen et al. notes that after the intake of antibiotics, health is promoted by repopulating the intestinal flora with Bifidobacteria (page 1, paragraph [0002]). Therefore, claim 13 is rendered obvious. Given that adhesion of pathogens or toxins produced by pathogens to the gut wall is prevented, and that normal gut flora is reestablished, the Dumortier galactooligosaccharide mixture would have been considered a product for improving gut health. Thus, claim 16 is rendered obvious. Claim 17 is also rendered obvious since galacto-oligosaccharides are suitable for use in yogurt, cheese, fermented milk products, dietary supplements, and probiotic comestible products.

Dumortier et al. differs from the claimed invention in that it does not expressly disclose that the galactooligosaccharide mixture is a substance for promoting the growth of bifidobacteria. At the time the invention was made, it would have been obvious to have used the Dumortier galactooligosaccharide mixture for promoting the growth of bifidobacteria. One of

ordinary skill in the art would have been motivated to do this since galactooligosaccharides are known to enhance the growth of bifidobacteria, as demonstrated by Jorgensen et al. and Ziggers. Thus, in teaching the manufacture of galactooligosaccharides by the treatment of lactose-containing material with a cell suspension of *B. bifidum*, Dumortier et al. renders claim 18 obvious. Claims 19 and 20 are rendered obvious since it would have been obvious to have substituted one known lactose-containing material with another. Moreover, Jorgensen et al. teaches that the lactose for oligosaccharide production can be present in a product selected from the group consisting of yoghurt, cheese, fermented milk products, dietary supplements, and probiotic comestible products (page 3, paragraph [0022]).

Dumortier et al. differs from the claimed invention in that it does not disclose that following the removal of the *B. bifidum* cells (which occurs as the cell suspension is centrifuged to obtain a supernatant solution, see page 116, last paragraph), the galactooligosaccharide mixture is spray-dried to produce a powder.

De Jong et al. discloses preparations having health-promoting actions which contain one or more probiotics and one or more non-digestible oligosaccharides (abstract). In one supplement, transgalacto-oligosaccharides (TOS) were dissolved in water and then spray-dried to obtain a powder which is used in a dietary supplement (page 7, last paragraph through page 8, first paragraph).

At the time the invention was made, it would have been obvious to have spray-dried to a powder the supernatant solution of the Dumortier invention containing the galactooligosaccharide mixture. One of ordinary skill in the art would have been motivated to do

this since spray-drying is a suitable method for obtaining TOS in a form for ingestion for health-promoting effects. Thus, claim 21 is rendered obvious.

A holding of obviousness is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
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